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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,351	10/31/2003	Ronald James Jandacek	9129L	2523

27752 7590 05/11/2011

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ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
05/11/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/699,351
Filing Date: October 31, 2003
Appellant(s): JANDACEK ET AL.

Cynthia L. Clay
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/02/2001 appealing from the Office action mailed 10/13/10.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1, 3, 5-7, 9-12 are finally rejected and are appealed. Claims 49-53 are withdrawn.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,703,369	de Smidt et al	3-2004
6,703,319	Maeder et al.	3-2004
5,750,585	Park et al.	3-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5-7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Smidt et al. (US 6,703,369) in view of Maeder et al. (US 6,730,319) and Park et al. (US 5,750,585).

The claims are directed to a composition comprising a stiffening agent having a complete melting point of about 33°C or greater, a lipase inhibitor and a non-digestible, non-absorbable, open-celled HIPE foam.

With regards to instant claim 1 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition as recited by instant claim 1 is a stiffening agent) or a fatty acid (see abstract and col. 1 lines 50+), wherein R is (12-20 carbon atoms; see col. 3, line 60), having a melting point of 37°C (i.e., greater than 33°C and

(ii) a lipase inhibitor (i.e., orlistat known also known as tetrahydrolipstatin, see col. 1 lines 46+ and col. 3, lines 27-35) wherein the ratio of the stiffening agent is at least 4.5:1 (see col. 4, lines 38-65), the stiffening agent varies between 0.5 and 90% and the lipase inhibitor varies from 1-50% (as required by instant claims I(a & b), 3, 5-7, 9-11, also see col. 2, lines 26-30). Intrinsically, one of ordinary skill in the art would routinely adjust the ratios based on the amount of either the lipase inhibitor or the stiffening agent to arrive at the claimed ratios recited in claims 7 and 9-11. For example if the stiffening agent present in an amount of 45% and the lipase inhibitor present is 10%, the ratio therefore is 4.5:1 or 90% of the stiffening agent to 20% of the lipase inhibitor.

However, de Smidt fails to teach the specific stiffening agent as calcium stearate, behenic acid and mixtures thereof as required by instant claim 12, and also fails to teach a non-digestible, non-absorbable, open-celled HIPE foam. Therefore Maeder and Park are added to remedy this deficit.

Maeder et al. teach a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point equal or greater than 37°C, (see col. 1 lines 7-21), wherein the fatty acid is selected from behenic acid (see col. 5, lines 43+) as in claims 1,3 and 12.

However Maeder et al. fails to teach a non-digestible, non-absorbable, open-celled HIPE foam.

Park et al. teach a non-digestible, non-absorbable, open-celled HIPE foam compositions and methods of orally administering said forms compositions for the treatment of obesity (see column 3, lines 15-25 and column 15, lines 16-32, as it relates to claim 1).

However, Park fails to teach a lipase inhibitor.

Although de Smidt fails to teach the specific stiffening agent and the non-digestible, non-absorbable, open-celled HIPE foam, it would have been obvious to one having ordinary skill in the art at the time the invention was made to expand the teachings of de Smidt to include a non-digestible, non-absorbable, open-celled HIPE foam in the drug delivery foam compositions disclosed by Park et al. for formulation of a composition for reducing fat absorption or for treating obesity, as taught by de Smidt.

One of ordinary skill in the art would have had reasonable expectation of success in the formulation of the composition for fat absorption and treatment of obesity because Park et al. teach that open-celled foam compositions can be used as oral drug delivery system, in oral dosage forms for reducing fat absorption and treating obesity.

(10) Response to Argument

Appellant argues on pages 3-6 that "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some apparent reason to combine or modify reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference(s), when combined or modified, must teach or suggest all the claim limitations. MPEP 2143".

Neither de Smidt, Maeder, nor Park teach or suggest all of the claim limitations of independent claim 1. First de Smidt, Maeder, and Park do not teach or suggest the stiffening agent as recited in claim 1. The current application claims and discloses ethers of fatty alcohols mono-functional alcohols (R-OR').

Specifically Applicant argues that a monoglyceride, as defined by de Smidt is an example of a polyol and a polyol is not a mono-functional alcohol therefore de Smidt does not teach independent claim 1 and Maeder does not teach the ratio of stiffing agent to lipase from at least 5:1.

Second, de Smidt, Maeder, and Park do not teach or suggest a non-digestible, non- absorbable, open-celled high internal phase emulsion (HIPE) foam as recited in claim 1, that Park the hydrogels of Park are prepared by introducing a gas into a

monomer solution comprising at least one hydrophilic olefin monomer compound. The hydrogels of Park are not formed from an emulsification process using hydrophobic monomers. The compositions of Park are formed by introducing gas into a hydrophilic olefin monomer solution during polymerization of the monomer. Thus, the compositions of Park and the present invention are not the same.

Appellants further argues that the present invention is directed to a composition useful for stiffening unabsorbed dietary fat and through such stiffening the viscosity of the substance in vivo resulting in the formation of solids, semisolids, pastes, and gels.

Finally Appellant argues that in arguendo that one were to combine de Smidt, Maeder, and Park one would still fall short of the Appellants' claimed invention only to arrive at a compositions that includes lipase inhibitors in combination with fatty acid esters of polyols, and a hydrogel that swells to form a physical barrier that reduces the amount of physical space in the stomach, and the composition is able to transform the active ingredient after oral ingestion from a solid to a liquid form.

In response Appellant's argument that neither de Smidt, Maeder, nor Park teach or suggest all of the claim limitations of independent claim 1 is found not persuasive for these reasons:

Maeder specifically teach that the term glyceride ester refers to an ester of glycerol wherein the esters can contain one or three C12-C20 and can be chosen from the group comprising **mono**glyceride (see col. 3, lines 58-64) specifically the monoglycerides can be chosen from monocarin, monolaurin, monomysristan and monopalmitin which represents the formula R-OR'. Therefore Appellant's argument that

the current application claims and discloses ethers of fatty alcohols mono-functional alcohols (R-OR') is found not persuasive.

The argument that de Smidt, Maeder, and Park do not teach or suggest a non-digestible, non- absorbable, open-celled high internal phase emulsion (HIPE) foam as recited in claim 1, that Park the hydrogels of Park are prepared by introducing a gas into a monomer solution comprising at least one hydrophilic olefin monomer compound. The hydrogels of Park are not formed from an emulsification process using hydrophobic monomers is found not persuasive because how Park formulates or makes the open celled high internal phase emulsion bears no relevant to the issue here. The claims are not directed to a process of making a HIPE but to using a HIPE, how it is prepared plays no role in this rejection and the Board should not consider Appellant's argument.

Appellant argument that the present invention is directed to a composition useful for stiffening unabsorbed dietary fat and through such stiffening the viscosity of the substance in vivo resulting in the formation of solids, semisolids, pastes, and gels is also found not persuasive because Appellants claims are to a composition and the intended use is given no patentable weight. Additionally, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Finally Appellant's argument that that if one were to combine de Smidt, Maeder, and Park one would still fall short of the Appellants' claimed invention only to arrive at a

compositions that includes lipase inhibitors in combination with fatty acid esters of polyols, and a hydrogel that swells to form a physical barrier that reduces the amount of physical space in the stomach, and the composition is able to transform the active ingredient after oral ingestion from a solid to a liquid form is found not persuasive because de Smidt specifically teach a stiffening agent having a complete melting point of 37℃ which is greater than 33℃, wherein the stiffening agent is R-OR' and a lipase inhibitor.

Summary: Even if in arguendo de Smidt fails to teach the stiffing agent which is not so, Maeda et al. teach a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point equal or greater than 37℃, (see col. 1 lines 7-21), wherein the fatty acid is selected from behenic acid (see col. 5, lines 43+ as in claims 1, 3 and 12 same as that defined by Appellant (see page 10, lines 10-14). Thus one of ordinary skill in the art would have substituted de Smidt's fatty acid with Maeder's as already made of record in office action mailed 7/30/09).

Although de Smidt fails to teach the specific stiffening agent and the non-digestible, non-absorbable, open-celled HIPE foam, it would have been obvious to one having ordinary skill in the art at the time the invention was made to expand the teachings of de Smidt to include a non-digestible, non-absorbable, open-celled HIPE foam in the drug delivery foam compositions disclosed by Park et al. for formulation of a composition for reducing fat absorption or for treating obesity, as taught by de Smidt.

One of ordinary skill in the art would have had reasonable expectation of success in the formulation of the composition for fat absorption and treatment of obesity because

Park et al. teach that open-celled foam compositions can be used as oral drug delivery system, in oral dosage forms for reducing fat absorption and treating obesity.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/S. V. G./

Examiner, Art Unit 1628

Conferees:

/Brandon J Fetterolf/

Supervisory Patent Examiner, Art Unit 1628

/SHAOJIA ANNA JIANG/

Supervisory Patent Examiner, Art Unit 1623